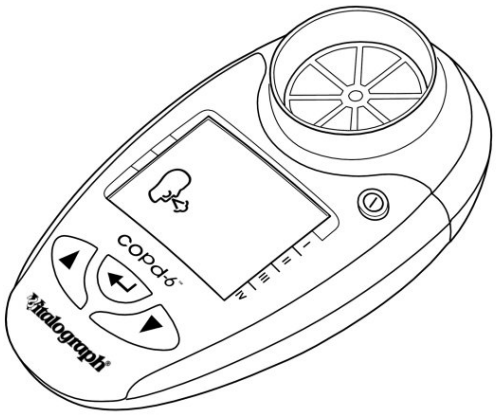
Vitalograph® COPD-6™

User Manual



Model No. 4000

Medical Devices Directive
93/42/EEC L169, Vol. 36.
EN ISO 13485
FDA QSR 21 CFR 820/803

Manufacturer: Vitalograph (Ireland) Ltd, Ennis, Ireland

Table Of Contents

Warnings and Advisory Notices 3

Main Components of the Vitalograph copd-6™ 4

What Is The Vitalograph copd-6™ Used For? 4

What Is The Vitalograph copd-6™ Used For? 5

How To Use The Vitalograph copd-6™ 5

Entering Subject Data *5*

Performing the Test *6*

Setting The Obstructive Index and COPD Classification Zones *7*

Reviewing the Last Session Test Results *8*

Care and Cleaning Of The Vitalograph copd-6™ 9

Table of Materials Used & Cleaning/Disinfection Methods *9*

Consumables, Accessories and Spare Parts 10

Explanation of Symbols 10

Technical Specifications 11

Warranty 11

Appendices 12

Quick Start Guide *12*

Regulatory Notices for the Vitalograph copd-6™ *13*

CE Notice *13*

FDA Notice *13*

Declaration of Conformity *15*

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Warnings and Advisory Notices

Note: Please read all the information in this manual before using the Vitalograph copd-6. A full set of instructions, including cleaning instructions, is available at www.vitalograph.co.uk.

- This Vitalograph device is intended to measure lung function for use in clinic with disposable mouthpieces or filters or for patient use at home under medical supervision.
- Take care not to block the mouthpiece with the tongue or teeth. A ‘spitting’ action or coughing will give false readings.
- If used at home symptoms must take precedence over device measurements*.
- If the device is used for longer than its specified life, the accuracy of the device may deteriorate.
- Before use, ensure that the batteries do not exceed their shelf life, as indicated on the batteries.
- Store in a clean dry place.

* If you suspect that a defect has occurred you should check the Vitalograph copd-6 for operation and accuracy.

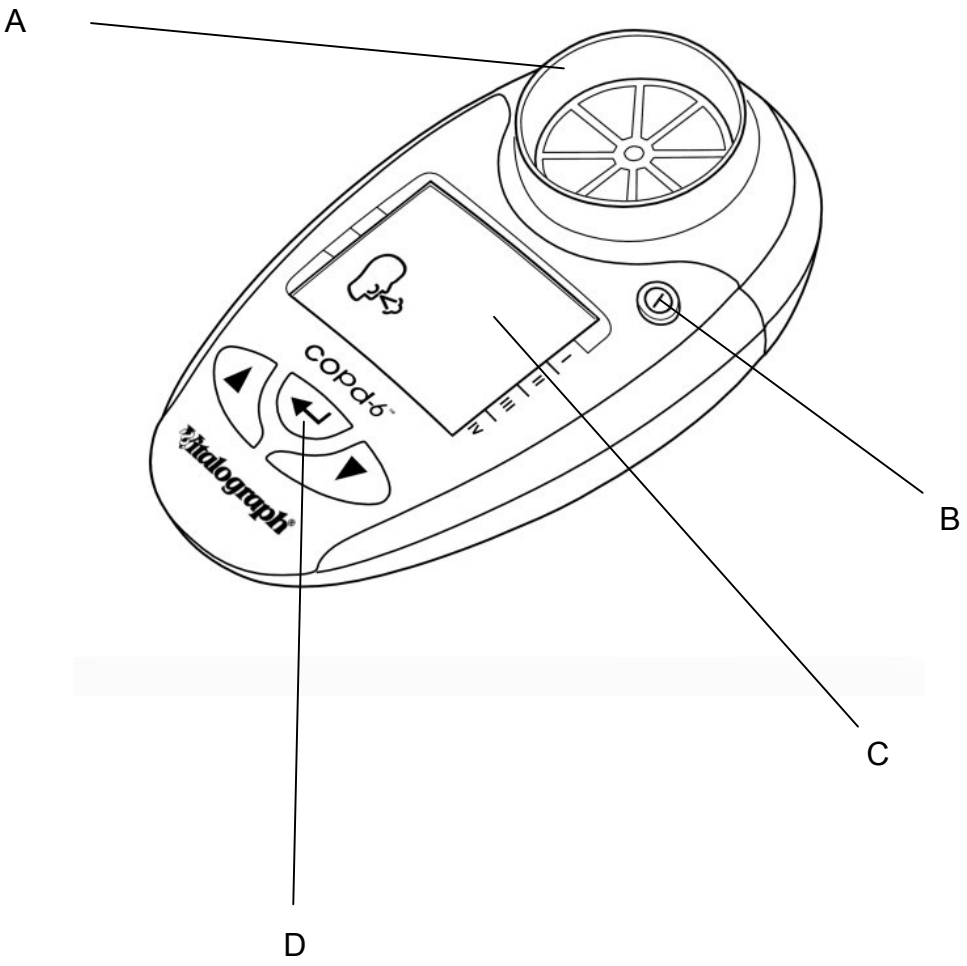
Main Components of the Vitalograph copd-6™

A Flowhead

B On / off button

C Display

D User buttons



What Is The Vitalograph copd-6™ Used For?

The Vitalograph copd-6 is a device intended for measuring lung function. It can be used by a healthcare professional or assistant as a rapid pre-spirometry test to screen-out at-risk individuals that do not have COPD and indicate those that may be at risk of COPD at the pre-symptomatic stage of the disease. This “screening” or “case selection” for full spirometry examinations may result in earlier medical intervention and facilitate better clinical outcomes.

The Vitalograph copd-6 displays some key parameters for clinical interpretation:

- FEV1 and FEV1 % Predicted
- FEV6 and FEV6 % Predicted
- FEV1/FEV6 and FEV1/FEV6 % Predicted

If an abnormal result is indicated, arrows on the display shows:

- Obstructive Index
- COPD Classification (stages I - IV)

How To Use The Vitalograph copd-6™

Entering Subject Data

The subject’s physical data can be entered into the Vitalograph copd-6 in order to calculate predicted data.

To enter the subject data, follow these steps:

1. Turn the device on, ⏻.
2. The age can now be set (). This is done by pressing the ▲ or ▼ button and releasing when the age is reached.
   The values will increase/decrease in values of 1. If the button is kept depressed, the values will scroll faster.
   Press the ↵ button to set the age.
3. The height can now be set (). This is done by pressing the ▲ or ▼ button and releasing when the height is reached.
   The values will increase/decrease in values of 1. If the button is kept depressed, the values will scroll faster.
   Press the ↵ button to set the height.
   Note: if height values are set below 100, the device assumes height is in inches and that Weight will be in lbs rather than Kg.
4. The gender can now be set (⚥). This is done by pressing the ▲ or ▼ button and releasing when the correct gender is showing (.Male (♂); Female (♀))
   Press the ↵ button to set the gender.

   After gender is selected, the Vitalograph copd-6 will go to Test Mode, where the Blow Icon is showing. On some variants, an additional data field comes first (see below).
5. (This step may be omitted, depending on the variant) The Population Group (on some variants this is Weight instead) can now be set (). This is done by pressing the ▲ or ▼ button and releasing when the desired setting is reached.

Press the ↵ button to set.

Set No.	Example Population Group
1	NHANES III Caucasian
2	NHANES III African-American
3	NHANES III Hispanic-American

Performing the Test

1) The subject should sit down when blowing into the device (unless advised otherwise). Insert a new disposable SafeTway mouthpiece into the device.
2) Turn the device on, ① (if not already ON). When the device is ready for a test the blow icon shows ( ).
3) Instruct the subject and demonstrate (using a mouthpiece) as follows:
   a) "Hold your head up, breathe in as deeply as possible, hold the device in front of your mouth".
   b) "Hold your breath, place the mouthpiece into your mouth, like this, bite the mouthpiece lightly, and seal your lips firmly around it, like this". I will demonstrate.
   c) "Blow out as HARD, and FAST as you can, like this, until I tell you to stop" (the unit will beep at end of test - after 6 seconds).
   d) "Be careful not to block the mouthpiece with your tongue or teeth. A 'spitting' action will give false readings".
   e) "Now you do it – deep breath in – bite and seal – blast the air out…keep going – keep blowing".
   f) "Well done!" "Now, we need to do that three times. Rest for a while until you are ready to blow again".
4) To view the result (the best values in the session), press the ↵ button.
   a) The COPD Classification will show on the right hand arrow.
      i) Green is NORMAL, negative for COPD. No need to refer this subject for spirometry.
      ii) Any one of the blue zones, I, II, II or IV are not normal. This subject should be referred for spirometry.
   b) The Obstructive Index (OI) shows on the left hand arrow.
      i) 0 - Green is normal.
      ii) 1, 2 or 3 – Yellow, amber or red are not normal. Refer for spirometry, but this is unlikely to be COPD.
      iii) Note: If the right hand (COPD) arrow is not green, nor will the left hand (OI) arrow be green.
5) This is the end of the test, but if desired some test parameters may be viewed.

6) Following each blow and at the end of the test session, the FEV1 value will be displayed and below that, FEV1 % Predicted results for that blow, or for the best in session if the ↵ button has been pressed. Pressing ↵ again will toggle between best and last blow.
7) Pressing the ▲ button will show the FEV6 and FEV6 % Predicted results.
8) Pressing the ▲ button again will show the FEV1/FEV6 and FEV1/FEV6 % Predicted results.
9) Press the ▲ button for a final time will show the estimated Lung Age ( ).

Notes on testing:

1) During testing, if an exclamation mark ! appears, this means that the last blow was not a good quality blow and the user should blow again. Reasons for poor quality are;
   a) Slow Start of test: Vext (extrapolated volume) is > 5% or 150mL of FEV6.
   b) Cough detected.
2) In the event that a test is < 3 seconds duration and has an abrupt end (change in volume is > 25ml in the last second of the test), the value FEV will be displayed instead of FEV6.
3) If the test subject experiences side effects such as dizziness or fatigue during the test procedure, stop testing until recovered.

Setting The Obstructive Index and COPD Classification Zones

The Vitalograph copd-6 Obstructive Index and COPD Classification zones are set by the manufacturer to the GOLD (**G**lobal Initiative for Chronic **O**bstructive **L**ung **D**isease) standard and it is unlikely that a user will wish to change this – however if this is required please follow the following instructions;

The colour systems for each zone type are pre-set as follows;

FEV1%Pred.	Obstructive Index		COPD Classification	FEV1/FEV6 Ratio and FEV1%Pred.
≥ 80%	0		Not COPD	FEV1/FEV6 > 0.7
		Top boundary	Stage I	FEV1/FEV6 < 0.70 and FEV1 ≥ 80% Pred.
< 80%	1	Middle boundary	Stage II	FEV1/FEV6 < 0.70 and FEV1 < 80% Pred.
< 50%	2	Bottom boundary	Stage III	FEV1/FEV6 < 0.70 and FEV1 < 50% Pred.
< 30%	3		Stage IV	FEV1/FEV6 < 0.70 and FEV1 < 30% Pred.

To set the boundary percentage values for both the Obstructive Index and COPD Classification zones together, follow these steps;

1. Turn the device on, ⏻.
2. When the icon appears, press and hold the ↵ and ▲ buttons for approximately 3 seconds.
3. The top boundary can now be set. This is done by pressing the ▲ or ▼ button and releasing when the value is reached.
   The values will increase/decrease in values of 1%. If the button is kept depressed, the values will scroll faster.

4. Press ↵ to set the top boundary value.
5. The middle boundary can now be set. This is done by pressing the ▲ or ▼ button and releasing when the value is reached.
   The values will increase/decrease in values of 1%. If the button is kept depressed, the values will scroll faster.
6. Press ↵ to set the middle boundary value.
7. The bottom boundary can now be set. This is done by pressing the ▲ or ▼ button and releasing when the value is reached.
   The values will increase/decrease in values of 1%. If the button is kept depressed, the values will scroll faster.
8. Press ↵ to set the bottom boundary value.
9. Press ↵. The device will return to the age entry screen.

Reviewing the Last Session Test Results

The Vitalograph copd-6 will always store the last test session, even after the device has powered itself down or has been switched OFF. In order to view the last test session, follow these steps;

1. Turn the device on, ⏻.
2. When the device is ready for age entry (), press the ↵ button for approximately 3 seconds. The last test session (best results) data will now show again.
3. When you have finished reviewing the data, press the OFF button for 3s. OR
4. Press ↵. The device will return to the age entry screen ready for entering the next test subject's data.

Care and Cleaning Of The Vitalograph copd-6™

A new mouthpiece (either SafeTway or BVF) should be used for each subject. A delay of at least 5 minutes should be allowed between subjects to allow settling of previously aerosolized particles in the measuring device.

It is recommended that the device be regularly cleaned according to the guidelines of the user's facility. The disinfection materials and procedures applied in the users' facility may be more appropriate than the methods outlined below. In the event of visible contamination of the flowhead element, it should be cleaned or disinfected as described in the accompanying table. The device should be replaced in the event of damage, or if visibly contaminated.

The frequency of cleaning and disinfecting is dependent on the facility's risk assessment, usage, and test environment, but it should be at least monthly or every 100 subjects (300 blows).

It is recommended that the device be replaced annually or test and calibration serviced at least annually. There is no planned preventive maintenance for this medical device.

Table of Materials Used & Cleaning/Disinfection Methods

This listing provides clinical users with information to allow the assessment of other suitable cleaning and disinfecting procedures available in their facility.

Part	Material	Cleaning Recommendation	Disinfection Recommendation
Body	PC/ABS	Wipe with a damp cloth	Alcohol wipe (IPA 70-90%)
Fascia	Polycarbonate	Wipe with a damp cloth	Alcohol wipe (IPA 70-90%)
Buttons	Synthetic Rubber	Wipe with a damp cloth	Alcohol wipe (IPA 70-90%)

All external parts of the Vitalograph copd-6 require cleaning, i.e. the removal of visible particulate contamination. Do not attempt to insert any object or to clean the rotor or stator in the measuring system.

This device is not designated as a 'sterile' device. Wiping with a 70% Isopropyl Alcohol impregnated cloth provides a suitable form of cleaning and low-level disinfection for the case exterior. Repeat this at least weekly to prevent a build-up of grime from normal handling and use.

Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals or equipment.

Definitions of cleaning and disinfection are as defined in "Sterilization, Disinfection and Cleaning of Medical Equipment:

Guidance on Decontamination from the Microbiology Committee to Department of Health Medical Devices Directorate, 1996"

Recommendations for chemical disinfectants are derived from the PHLS publication "Chemical Disinfection in Hospitals" 1993.

Consumables, Accessories and Spare Parts

Cat. No	Description
20242	SafeTway Mouthpieces (200)
20303	Disposable Noseclips (200)
20980	Mini SafeTway® mouthpieces (50)
28350	BVF® Bacterial/Viral Filters (50)

Explanation of Symbols

Device symbols;

Type BF equipment

Class II

The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste.

Attention (reference relevant section in manual)

User Interface Symbols;

Battery status: Full

Battery status: Half

Battery status: Empty (flashing)

Blow Now Symbol

!
Bad Test Symbol (Slow start or Cough)

kglb
Unit of weight measurement

Lung Age Symbol

Age Symbol

Height Symbol

Gender Symbol

Population Group Symbol

Technical Specifications

Material:	PC/ABS
Accuracy:	Better than ± 3%
Flow Impedance:	Better than 0.15kPa/L/s at 14L/s
Measurement Range:	0 – 9.99 L BTPS
Performance And Safety Standards:	ATS/ERS Guidelines 2005
Electromagnetic emissions:	CISPR 11 Group 1 (battery operated)
Electromagnetic immunity:	IEC 61000-4-2, IEC 61000-4-3 (battery operated)
Sensor	Stator/rotor
Power Supply	2 x AAA batteries
Operating Temperature	17 – 37°C
! Bad Test Criteria	Slow start of test (Vext>5%) or a cough detected in the first second
FEV substituted for FEV6	When FET < 3s and abrupt end of test
Auto power down time	Set to 2 minutes as standard

Warranty

Your Vitalograph copd-6 is guaranteed for one year*. Replace if it is faulty, otherwise replace the unit every three years.

* Excepting accidental / transit damage or inappropriate use of the device.

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Appendices

Quick Start Guide

Prepare Device

1. ⏻ Switch On.

2. Set test subject's age.

Press ▲ or ▼ to change age.

Press ↵ to set.

3. Set test subject's height.

Press ▲ or ▼ to change height.

Press ↵ to set.

4. Set test subject's gender.

Press ▲ or ▼ to change gender.

Press ↵ to set.

5. Set test subject's population group.

Press ▲ or ▼ to change population group.

Press ↵ to set.

No.	Population Group	Ref
1	European (default)	ERS 1993
2	Chinese	ERS 1993
3	Japanese	ERS 1993
4	Polynesian	ERS 1993
5	Asian	ERS 1993
6	African	ERS 1993
7	Caucasian	NHANES III
8	African-American	NHANES III
9	Mexican-American	NHANES III
or		
20 and above	Weight (weight not normally required)	kg

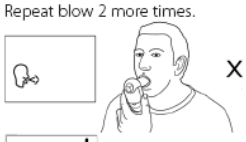
Perform Test

1. Insert disposable SafeTway mouthpiece.

2. Demonstrate to test subject.

- ▼ Fully breathe in, hold ...
- ▼ Insert and lightly bite the mouthpiece
- ▼ Then blow as hard as possible for 6 s (wait for beep)
- ▼ WELL DONE! Rest test subject for a short while and wait for blow icon to reappear

3. Repeat blow 2 more times.



= Bad blow

Test Result

1. Press ↵ to show result

Negative

Negative

- ▼ Spirometry not required
- ▼ COPD Classification green

Positive

Positive

- ▼ Refer for spirometry
- ▼ COPD Classification I to IV

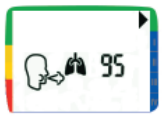
View Parameters

1. Display shows FEV1 and % of predicted.

2. Press ▼ to show FEV6 and % of predicted.

3. Press ▼ to show FEV Ratio and % of predicted.

4. Press ▼ to show Lung Age.



www.vitalograph.co.uk

Regulatory Notices for the Vitalograph copd-6™

CE Notice

Marking by the symbol CE 0086 indicates compliance of the Vitalograph copd-6 to the Medical Devices Directive of the European Community. Such marking is indicative that the Vitalograph copd-6 meets or exceeds the referenced technical standards.

The Vitalograph copd-6 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

The Vitalograph copd-6 is battery operated and is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

The Vitalograph copd-6 is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

- Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
- Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
- Interference may occur in the vicinity of equipment marked with the following symbol - .

FDA Notice

Caution: Federal Law restricts this device to sale by, or on the order of a physician.

Recommended separation distances between portable and mobile RF communication equipment and the system

The Vitalograph copd-6 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5GHz** $d = 2.3\sqrt{P}$
0.01	0.1m	0.1m	0.2m
0.1	0.4m	0.4m	0.7m
1	1.2m	1.2m	2.3m
10	3.7m	3.7m	7.4m
100	11.7m	11.7m	23.3m

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

Note 1: at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Declaration of Conformity

Product: Vitalograph copd-6™

Vitalograph hereby ensures and declares that the above product associated with this user manual, is designed and manufactured in accordance with the following QMS regulations and standards:

European Medical Devices Directive {MDD} 93/42/EEC.
This device, classified as 2a as per Annex IX of MDD 93/42/EEC, meets the following provisions of Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.
This device complies with the EMC Directive 89/336/EC, conformance demonstrated by following standard EN60601-1-2:2001. Equipment classification: Residential.

CE 0086

Canadian Medical Device Regulation {CMDR}

FDA Quality System Regulation {QSR} 21 CFR 820.

EN ISO 13485: 2003. Medical devices. Quality management systems. Requirements for regulatory purposes.

Certifying Body {for 93/42/EEC and CMDR}: British Standards Institute {BSI}

Certificate Nos. CE 00772, MD 82182, FM 83550